



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0645; FRL-9978-03]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0574.18); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: “Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances” and identified by EPA ICR No. 0574.18 and OMB Control No. 2070-0012, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before *[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0645, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Adam Ross, Chemical Control Division (7101M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1625; email address: ross.adam@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances.

ICR number: EPA ICR No. 0574.18.

OMB control number: OMB Control No. 2070-0012.

ICR status: This ICR is currently scheduled to expire on November 30, 2018. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The

OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that any person who proposes to manufacture (which includes import) a “new chemical” (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a notice to EPA at least 90 days prior to commencing manufacture of that chemical. EPA must review a section 5 notice, make an affirmative determination on the safety of the new chemical substance, and, if appropriate, regulate the chemical to address any unreasonable risks identified before it can proceed to the marketplace.

EPA is authorized to determine that a use of a chemical substance is a significant new use and promulgate a significant new use rule (SNUR). In certain instances, persons may opt to pursue that use, in which case they must submit a notice and undergo a review. For such circumstances, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture or process a chemical for a use that is determined by EPA to be a “significant new use.”

Furthermore, TSCA section 5 requires EPA to make determinations regarding the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses. To assist in the evaluation, EPA encourages notice submitters to contact an EPA specialist through a pre-submission consultation to ensure that the submitter understands EPA's review process and information needed to make a determination regarding the chemical. On June 20, 2018, EPA issued guidance entitled "*Points to Consider When Preparing TSCA New Chemical Notifications*" to inform and assist submitters planning to prepare notices, and exemption applications for Agency review (see <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca>). Using the notice submitted to the Agency, EPA evaluates the health and environmental effects of new chemical substances. On the basis of its review, EPA must make one of five possible regulatory determinations with respect to the new chemical substance or significant new use and take action, as appropriate, to ensure adequate protection of human health and the environment. If EPA takes no action within the 90-day review period for PMNs (or 30 or 45 days for PMN exemption applications), the Lautenberg amendments state that the PMN submitter is entitled to receive a refund of fees. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement

This information collection addresses the reporting and recordkeeping requirements associated with TSCA section 5.

Responses to the collection of information are mandatory (see 40 CFR parts 700, 720, 721, 723 and 725). Respondents may claim all or part of a document confidential.

EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between approximately 17 and 524 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are companies that manufacture, process or import chemical substances.

Estimated total number of potential respondents: 234.

Frequency of response: Annual.

Estimated total average number of responses for each respondent: 1,795.

Estimated total annual respondent burden hours: 148,312 hours.

Estimated total annual respondent costs: \$ 46,765,6135. This includes an estimated burden cost of \$ 138,093 and an estimated cost of \$ 0.00 for capital investment or maintenance and operational costs.

III. Are There Changes in the Estimates from the Last Approval?

There is an increase of 146,312 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects a change in the mix of EPA's estimated number of each type of notice. Similarly, the estimated number of annual CDX registrants also increased. Lastly, there was an

increase in burden associated with new CBI substantiation requirements resulting from the 2016 amendment to TSCA. The change in burden is explained more fully in the ICR Supporting Statement. This change is an adjustment and a program change.

IV. What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 13, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

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